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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,111	09/15/2000	Charles J. Davidson	S63.2H-12013-US01	3759
490	7590	11/16/2005		
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			EXAMINER PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,111

Applicant(s)

DAVIDSON ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-19,42-48,50-70,72 and 73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-19,42-48,50-70,72 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

Claims 1, 3, 4, 7, 14, 57, 67, 69, and 72 are objected to because of the following informalities:

Regarding claim 1, on line 14, "bole" is a misspelling for "hole."

On line 7 of claim 1, the comma followed by a semicolon constitutes a typographical error.

Claims 3 and 4 have the same scope. If the base claim is allowed in the future, one of these claims will have to be cancelled.

With regard to claim 7, the claim ends with a comma.

With regard to claims 14, 57, and 69, "the catheter body" lacks antecedent basis.

With regard to claim 67, the claim does not end with a period.

With regard to claim 72, since the guidewire is not positively claimed, the language of the last line confuses whether the guidewire is positively required.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

Claims 1, 3-8, 10-19, 42-48, and 50-70 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Particularly, the claimed invention is claimed as being inserted into the body where the base claims state, "wherein the stent hole is substantially aligned with the branch vessel." The Examiner suggests changing "aligned" to "alignable" in order to overcome this objection.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In claim 72, lines 13-15, “the distal portion of the side member disposed beneath . . . the stent is capable of being moveable with respect to the catheter” does not have clear antecedent basis from the specification and is not clearly shown in the drawings.

Similarly, in claim 73, lines 8-9, the language “a distal portion of the side member is disposed beneath . . . the stent and is capable of being positioned within a side branch” does not have clear antecedent basis.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, in claim 72, lines 13-15, “the distal portion of the side member disposed beneath . . . the stent is capable of being moveable with respect to the catheter” must be clearly shown in the drawings. Similarly, in claim 73, lines 8-9, “a distal portion of the side member is disposed beneath . . . the stent and is capable of being positioned within a side branch” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 6-8, 10-13, 15, 18, 45-48, 50-56, 58-60, 63, 65, 70, and 72-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Colombo et al (US 6,520,988) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colombo et al (US 6,520,988) alone. Colombo anticipates the claim language where the markers can be put on all the elements including both dilators and on the side port (19) of the stent; see column 12, line 52 to column 13, line 20. These markers or indicators are all juxtapositioned in one configuration prior to deployment and located near or at the side port. The side member of Colombo is fixedly attached to the main catheter at least by the stent. The branch stent deployment device as claimed is the balloon portion of the side branch; see Figures 1 to 6.

Alternatively, one could view the markers of Colombo as not being positively juxtapositioned with respect to each other. However, since the markers are to locate the relative position of the stent near the vessel and to detect some change in the configuration, it is the Examiner's position that the putting them adjacent to one another would have been considered clearly obvious to an ordinary artisan.

With regard to claims 50 and 73, it is not clear disclosure that the markers of Colombo are adjacent each other in one configuration and separated in a second configuration. However, since they are separate markers on different elements, they could be considered separated even when they are adjacent each other. Furthermore, it would have been considered at least obvious to have the markers become more separate in view of Colombo alone because a noticeable change in the configuration was contemplated by Colombo; see column 13, lines 3-20.

Claims 5, 16, 17, 19, 42-44, 61, 62, 64, 66, and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colombo et al (US 6,520,988) alone.

Regarding claims 16, 17, 61, and 62, Colombo fails to disclose a balloon inflation lumen, channels, and ports. However, since Colombo discloses balloons that can be inflated by an operator of the device, it would have been obvious to have a lumen with channels and ports to deliver the inflation fluid to the balloons. In other words, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have such features in Duffy because Applicants have not disclosed that having such provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the a functional set of balloons is all that is necessary. Therefore, it would have been an obvious matter of design choice to modify Duffy to obtain the invention as specified in the claims.

Regarding claims 19 and 64, Colombo fails to disclose the length of the detachment of the elements designated as the catheter and side member. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a 2 to 10 cm detachment length because Applicants have not disclosed that having such provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because it would be suitably sized for the particular bifurcation point. Therefore, it would have been an obvious matter of design choice to modify Colombo to obtain the invention as specified in the claims.

With regard to claim 42-44 and 66-68, Colombo discloses attaching the main and side catheters together with at least the stent but not at some proximal part as claimed. However, since the Colombo teaches attachment of the elements together via the stent, it is the Examiner's position that it would have been obvious to attach the two elements together in some fashion particularly at the proximal end.

Regarding claim 69, Colombo fails to disclose a connector as claimed. However, since the stent performs the same function as a connector and since one could designate one module as the connector, the claimed invention would have been at least *prima facie* obvious to an ordinary artisan.

Claims 14 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colombo as applied to claims 1, 3, 4, 6-8, 10-13, 15, 18, 45-48, 50-56, 58-60, 63, 65, 70, and 72-73 above, and further in view of Davila et al (US 5,851,464). Colombo fails to disclose the use of pebax and graphite in the catheters. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to make the catheter of Davila out of pebax and graphite for the same reasons that Davila did the same and in order to promote sliding between the catheter and guidewire.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738